IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

JOSHUA DAVID FRISKE, Individually and as Personal Representative of the Estate of KATHRYN FRISKE; JEREMY FRISKE, Individually and as Personal Representative of the Estate of KATHRYN FRISKE; BILLY RAY STAPP; and GLORIA STAPP,	§	CIVIL ACTION NO.: 3:11–CV–00130–F
Plaintiffs,	§	
V.	§	
ALZA CORPORATION; and SANDOZ, INC.,	§	
Defendants.	§	

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION FOR PARTIAL DISMISSAL AND ALTERNATIVE MOTION FOR LEAVE TO AMEND THEIR COMPLAINT

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TO THE HONORABLE U.S. DISTRICT COURT:

COME NOW, Joshua David Friske, Individually and as Personal Representative of the Estate of Kathryn Friske; Jeremy Friske, Individually and as Personal Representative of the Estate of Kathryn Friske; Billy Ray Stapp; and Gloria Stapp, Plaintiffs herein and file this Response in Opposition to Defendants

ALZA Corporation and Sandoz, Inc.'s Motion for Partial Dismissal and Alternative Motion for Leave to Amend Their Complaint, and would respectfully show the court:

I.
FACTUAL BACKGROUND

This cause of action arises out of the wrongful death of Kathryn Friske, and is maintained by her parents and surviving children. Ms. Friske was 49 years old at the time of her death. She was prescribed fentanyl to manage chronic pain caused by fibromyalgia and osteoarthritis, and for this purpose she used a transdermal fentanyl patch that was designed, manufactured, advertised, marketed, sold and/or supplied by Defendants.

Defendants' transdermal patch (hereafter, "Patch") is an adhesive patch worn on the skin that is intended to secrete the opioid fentanyl such that the user absorbs the drug through her skin at a specific rate. However, the Patch Ms. Friske used at the time of her death secreted fentanyl at a rate that caused her to have a fatal overdose.

Plaintiffs brought this action, stating claims for strict product liability, defective manufacturing, defective marketing, defective design, negligence,

negligent misrepresentation, breach of implied warranty of fitness, and gross negligence. In response to Plaintiffs' Original Complaint, Defendants filed a partial motion to dismiss, alleging that Plaintiffs failed to adequately state claims for defective marketing, negligent misrepresentation, defective design and breach of the implied warranty of fitness. Defendants' motion does not challenge Plaintiffs' claims for strict product liability, defective manufacturing, negligence or gross negligence.

II.
ARGUMENT AND AUTHORITIES

Motions to dismiss under Rule 12(b)(6) are viewed with disfavor and are rarely granted.[1] When considering Defendants' motion to dismiss, the Court must construe the factual allegations in the complaint in the light most favorable to Plaintiffs.[2] If the factual allegations are plausible, the Court cannot decide disputed fact issues.[3] That is, the Court must assume that all plausible facts contained in the

[1]*Lormand v. U.S. Unwired, Inc.*, 565 F.3d 228, 231 (5th Cir. 2009)

[2]*Barker v. Riverside County Office of Educ.*, 584 F.3d 821, 824 (9th Cir. 2009); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007).

[3]*Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

complaint are true.[4] A complaint does not need detailed factual allegations, but must provide Plaintiffs' grounds for entitlement to relief– including factual allegations that when assumed to be true raise a right to relief above the speculative level.[5] If the complaint provides fair notice of the claim and the factual allegations are sufficient to show that the right to relief is plausible, the court should deny Defendants' motion.[6]

A. Plaintiffs adequately stated a claim for defective marketing

Defendants argue that Plaintiffs failed to adequately state a claim for defective marketing because Plaintiffs did not rebut an evidentiary presumption in favor of Defendants.[7] It is unnecessary for Plaintiffs to do so for the reasons that follow.

1. A rebuttable presumption is an evidentiary provision, not a rule of pleading

Courts generally refuse to consider presumptions and other evidentiary

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[4]*Id.*

[5]*Twombly*, 550 U.S. at 555-56.

[6]*See Ashcroft v. Iqba*l, ___ U.S. ___, 129 S. Ct. 1937, 1949 (2009); *Twombly*, 550 U.S. at 555-56.

[7]Def. Mot. at pgs. 3-15.

standards at the pleading stage.[8] No rule requires Plaintiffs' to preemptively rebut in their complaint any and all evidentiary presumptions to which Defendants may ultimately be entitled.[9] Rather, a presumption is met or rebutted by the party against whom it is made by "going forward with *evidence*."[10] It is axiomatic that the allegations in pleadings are not evidence.[11]

In civil actions, the effect of a presumption concerning a fact that is an element of a claim or defense as to which State law supplies the rule of decision is determined in accordance with state law.[12]

The long-established State law of Texas is that presumptions can never be made to subserve the primary function of direct evidence.[13] While Texas has not

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[8]*In re Elec. Data Sys. Corp. "ERISA" Litig.*, 305 F.Supp.2d 658, 668 (E.D.Tex. 2004); *See also, Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 510-14 (2002).

[9]See FED. R. EVID. 301; TEX. CIV. PRAC. & REM. CODE § 82.007.

[10]FED. R. EVID. 301 (emphasis added); *Farley v. M M Cattle Co.*, 529 S.W.2d 751, 756 (Tex. 1975) ("the office of a true presumption is to invoke a rule of law that compels the jury to reach a conclusion in the absence of *evidence to the contrary*.") (emphasis added).

[11]*In re Grand Jury Subpoena*, 419 F.3d 329, 336 (5th Cir.2005); *Laidlaw Waste Sys. (Dallas), Inc. v. City of Wilmer*, 904 S.W.2d 656, 660-61 (Tex. 1995).

[12]FED. R. EVID. 302.

[13]*See White v. Smyth*, 214 S.W.2d 967, 974 (Tex. 1948); 35 Tex. Jur. 3d Evidence § 108 (West 2002).

adopted a rule of evidence comparable to Federal Rule of Evidence 301, Texas common law provides that the effect of a presumption is to place upon the party against whom it is made the burden of *producing evidence* sufficient to justify the nonexistence of the presumed fact.[14] Texas State and Federal Courts have reiterated this rule with regard to the legal effect of the presumption that adequate warnings on products will be heeded:

> [The "read-and-heed" presumption] places upon the defendant in a failure-to-warn case the burden of *going forward with the evidence* on causation. If ... [the] defendant offers evidence contrary to the presumption, then [the] plaintiff must prove causation by a preponderance of the evidence, and the presumption has no further legal consequence.[15]

The "read-and-heed" presumption does not, for instance, entitled a Plaintiff to summary judgment on the issue of causation.[16]

Moreover, Defendants cite no controlling authority, and Plaintiffs find none,

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[14]*DaimlerChrysler Corp. v. Hillhouse*, 161 S.W.3d 541, 550 (Tex.App.–San Antonio 2004, pet. granted, judgm't vacated w.r.m.) (*citing General Motors Corp. v. Saenz*, 873 S.W.2d 353, 359 (Tex.1993)) (emphasis added).

[15]*Id*. (emphasis added). *See also Ackerman v. Wyeth Pharma.*, 526 F.3d 203 (5th Cir. 2008) ("The read-and-heed presumption's effect 'is to shift the burden of producing evidence to the party against whom it operates.' " *quoting General Motors Corp. v. Saenz*, 873 S.W.2d 353, 359 (Tex.1993).).

[16]*See id.*

suggesting that Rule 8(a)'s notice pleading requirement demands preemptive rebuttal of evidentiary presumptions. In fact, a Federal Court in the Eastern District of Texas held that "requiring Plaintiffs to affirmatively plead facts overcoming [a] ... presumption violates Rule 8(a)'s notice pleading requirement."[17] In the case of *In re Elec. Data Sys. Corp. "ERISA" Litigation*, the plaintiffs alleged that the defendants breached their fiduciary duties by offering employer stock as a "Plan investment," and that defendants knew this stock was not a prudent investment.[18] Defendants moved to dismiss under Rule 12(b)(6) on the grounds that the plan was an employee stock option plan ("ESOP") and there is a legal presumption that it is prudent to invest an ESOP in employer stock.[19] The defendants relied heavily on an opinion of a Rhode Island Federal District Court that held the plaintiffs must affirmatively plead facts sufficient to overcome the ESOP presumption.[20] The Texas Court explicitly rejected the Rhode Island Court's holding, relying on the United States Supreme Court's opinion in

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[17] *In re Elec. Data Sys. Corp. "ERISA" Litig.*, 305 F.Supp.2d at 670.

[18] *Id*. at 667.

[19] *Id*. at 668.

[20] *Id*. *citing Lalonde v. Textron, Inc.*, 270 F.Supp.2d 272, 280 (D.R.I. 2003).

Swierkiewicz v. Sorema N.A.[21] Following *Swierkiewicz*, the Eastern District Court stated that:

> the federal rules of civil procedure establish a liberal notice pleading requirement that allows broad access to discovery and relies on motions for summary judgment to eliminate claims lacking merit.[22]

The Court noted that the reason for this approach is that:

> Litigants are entitled to discovery before being put to their proof, and treating allegations of the complaint as a statement of the party's proof leads to windy complaints and defeats the function of Rule 8.[23]

The possibility that the discovery process could establish that the ESOP presumption would be inapplicable was central to the Court's rejection that the presumption itself entitled Defendants to dismissal.[24]

The *Electronic Data Systems* defendants' argument is directly analogous to Defendants' arguments in this case. Defendants argue that the Friske patch's warning must be presumed adequate, that Plaintiffs did not plead sufficient facts to overcome this presumption, and therefore the defective marketing claim must be

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[21]*In re Elec. Data Sys. Corp. "ERISA" Litig.*, 305 F.Supp.2d at 669-70.

[22]*Id*. at 669, *citing Swierkiewicz*, 534 U.S. at 512-14.

[23]*Id*. at 669 n.19, *quoting Bennett v. Schmidt*, 153 F.3d 516, 519 (7th Cir. 1998).

[24]*Id*. at 670.

dismissed.[25] What Defendants fail to acknowledge is that the presumption of adequacy is an evidentiary standard that is not appropriately considered at the pleadings stage.[26] Plaintiffs have no duty to plead facts rebutting the presumption of adequacy.[27] As were the plaintiffs in *Electronic Data Systems*, Plaintiffs in this case are entitled to conduct discovery and rebut any presumptions with evidence.

2. The holdings in Twombly and Iqbal do not require Plaintiffs to rebut presumptions that may be raised by Defendants in their pleadings.

The *Twombly* and *Iqbal* opinions require only that Plaintiffs state enough facts to state a claim to relief that is plausible on its face.[28] The issue in *Twombly* was whether or not the plaintiffs adequately stated a claim for restraint of trade under the Sherman Act.[29] An essential element of the *Twombly* plaintiffs' claim was the formation a "contract, combination ..., or conspiracy in restraint of trade or commerce."[30] The Court determined that the complaint could not survive

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[25]Def. Mot. at pgs. 3-15.

[26]*In re Elec. Data Sys. Corp. "ERISA" Litig.*, 305 F.Supp.2d at 669; *Swierkiewicz*, 534 U.S. at 512-14.

[27]*In re Elec. Data Sys. Corp. "ERISA" Litig.*, 305 F.Supp.2d at 670.

[28]*Iqbal*, 129 S. Ct. at 1949; *Twombly*, 550 U.S. at 555-56.

[29]*Twombly*, 550 U.S. 548-49.

[30]*Id*. at 548.

without "some factual context *suggesting* agreement."[31]

In reaching its determination, the Court held that "asking for plausible grounds to infer [an element of a plaintiff's claim] does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of [the claim's elements]."[32] That is, at the pleading stage, the threshold requirement of Rule 8(a)(2) is that the pleader make allegations that plausibly suggest the necessary elements of his claim.[33] This was restated in the *Iqbal* opinion: "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."[34]

The Supreme Court explained in *Twombly* that the "accepted pleading standard" is that "once a claim has been stated adequately, it may be supported by

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[31] *Id*. at 549 (emphasis added).

[32] *Id*. at 556.

[33] *Id*. at 556-57.

[34] *Iqbal*, 129 S. Ct. at 1949

showing any set of facts consistent with the allegations in the complaint."[35] This means that a plaintiff need not allege additional facts that may be necessary at the trial stage to support a claim.[36] In fact, the *Twombly* opinion noted that it is impermissible for a Court to dismiss a case for failure to plead " 'specific facts' beyond those necessary to state his claims and the ground showing entitlement to relief."[37]

At the trial stage, it may be necessary for Plaintiffs to show facts rebutting the presumption raised by section 82.007 of the Civil Practices and Remedies Code. However, requiring Plaintiffs to preemptively rebut evidentiary presumptions in favor of Defendants effectively requires Plaintiffs to plead specific facts beyond those necessary to establish the elements of their claims, contrary to the standard enunciated in *Twombly*.

3. Plaintiffs have stated enough facts to raise a reasonable expectation that discovery will reveal evidence of the elements necessary to recover for defective marketing

Plaintiffs have adequately pleaded enough facts to establish a claim for

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[35]*See Twombly*, 550 U.S. at 563.

[36]*Id.*

[37]*Id. citing Swierkiewicz v. Sorema N. A.*, 534 U.S. 506, 508 (2002).

defective marketing and grounds for relief, and the question of whether Defendants are entitled to a presumption that their warning was adequate is immaterial at the pleading stage, as explained above.

A marketing defect occurs when a defendant knows or should have known of a potential risk of harm presented by the product but markets it without adequately warning of the danger or providing instructions for safe use.[38] The elements that must be proved to recover for a marketing defect are as follow: (1) a risk of harm that is inherent in the product or that may arise from the intended or reasonably anticipated use of the product must exist; (2) the product supplier must actually know or reasonably foresee the risk of harm at the time the product is marketed; (3) the product must possess a marketing defect; (4) the absence of the warning and/or instructions must render the product unreasonably dangerous to the ultimate user or consumer of the product; and (5) the failure to warn and/or instruct must constitute a causative nexus in the product user's injury.[39]

In support of their claim of defective marketing, Plaintiffs pleaded that the

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[38]*Dewayne Rogers Logging, Inc. v. Propac Industries, Ltd.*, 299 S.W.3d 374, 384 (Tex. App.–Tyler 2009, pet. filed).

[39]*Id.*

fentanyl patch made the subject of this litigation, ("the Friske patch") was defective because patches such as the Friske patch could and did leak a powerful narcotic called fentanyl at a rate faster than intended, sometimes resulting in fatal overdoses.[40] Plaintiffs pleaded that Defendants had actual notice of this risk of harm at all relevant times, but continued to market the product without a warning addressing the risk of overdose due to malfunction of the patch when used normally, making them unreasonably dangerous.[41] Plaintiffs pleaded specifically that Defendants previously recalled leaking patches, prompting an investigation by the FDA which revealed defects in addition to those made the basis of the recall.[42]

Plaintiffs' claim plainly states facts demonstrating that it is plausible that the Friske patch was sold without a warning of the possibility that it could leak, causing injury and that the patch did leak, causing injury.[43] Specifically, Plaintiffs alleged that fentanyl patches matching the description of those used by the

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[40]Plaintiffs' Original Complaint at 7.

[41]*Id*. at 7-8.

[42]*Id*. at 8-9.

[43]*See id*. at pg.9, ¶19.

decedent were discovered to leak and cause overdoses[44], that Defendants should have reasonably foreseen the risk that the patches could leak and cause overdoses[45], that Defendants failed to provide a warning that leaking patches could cause overdoses and death[46], and that a leak in the Friske patch did cause Kathryn Friske's overdose and death.[47]

B. Plaintiffs adequately stated a claim for negligent misrepresentation

1. Plaintiffs need not plead facts rebutting a presumption that the Patch's warning was adequate

Just as Plaintiffs adequately stated a claim for defective marketing, Plaintiffs likewise adequately stated a claim for negligent misrepresentation. Defendants challenge Plaintiffs' negligent misrepresentation claim on the same grounds that they challenge Plaintiffs' claim for failure to warn.[48] Plaintiffs fully incorporate herein the arguments of sections A1 and A2, *supra*, as though fully set forth at length.

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[44]*Id*.

[45]*Id*. at pgs. 8-9, ¶¶ 18 & 19.

[46]*Id*. at pg. 13, ¶13.

[47]Plaintiffs' Original Complaint at pg. 6, ¶8.

[48]Def. Mot. at pgs. 15-16.

2. Plaintiffs have stated enough facts to raise a reasonable expectation that discovery will reveal evidence of the elements necessary to recover for negligent misrepresentation

The Texas Supreme Court has explicitly adopted the elements of negligent misrepresentation set forth by the RESTATEMENT (SECOND) OF TORTS § 552.[49] The elements that must be proved to recover for negligent misrepresentation are: (1) defendant made a representation to the plaintiff in the course of defendant's business, (2) the defendant supplied false information for the guidance of others, (3) the defendant did not use reasonable care in obtaining or communicating the information, (4) the plaintiff justifiably relied on the defendant's representation and (5) the defendant's negligent misrepresentation proximately caused the plaintiff's injury.[50]

In support of their claim for negligent misrepresentation, Plaintiffs pleaded that after Defendants knew that proper use of the Patch could cause injury or death, Defendants continued to represent that the patch was safe, that the decedent used the Patch in justifiable reliance on Defendants' representation that the Patch was

[49] *McCamish, Martin, Brown & Loeffler v. F.E. Appling Interests*, 991 S.W.2d 787, 791 (Tex. 1999).

[50] *Id. citing* RESTATEMENT (SECOND) OF TORTS § 552.

safe for use, and Defendants' misrepresentation of the safety of the Patch was a proximate cause of decedent's overdose and death.[51]

Specifically, Plaintiffs pleaded that the Friske patch was dangerous because patches such as the Friske patch could and did leak a powerful opiate narcotic at a rate faster than intended, causing fatal overdoses.[52] Plaintiffs pleaded that Defendants had actual notice of this risk, evidenced by product recalls and FDA investigations, but Defendants continued to distribute patches without a warning addressing the risk of overdose when the patch was used normally.[53] Plaintiffs pleaded specific facts in support of this contention, stating that Defendants previously recalled leaking patches, prompting an investigation by the FDA which revealed defects in addition to those made the basis of the recall.[54] Plaintiffs also pleaded facts showing that the decedent used the patch in reliance on Defendants' representations that the Patch was safe, that the patch she was wearing malfunctioned and that the malfunction of the patch proximately caused a fatal

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[51]Plaintiffs' Original Complaint at 7-9; 16.

[52]Plaintiffs' Original Complaint at 7.

[53]Plaintiffs' Original Complaint at 7-8.

[54]*Id*. at 8-9.

overdose of fentanyl.[55]

Plaintiffs' claim plainly states facts demonstrating that it is plausible that Kathryn Friske justifiably relied on Defendants' negligent misrepresentations that the Patch was safe for use, and her subsequent use of the Patch in reliance on Defendants representation proximately caused her death. Specifically, Plaintiffs pleaded that fentanyl patches matching the description of those used by the decedent were discovered to leak and cause overdoses[56], that Defendants should have reasonably foreseen the risk that the patches could leak and cause overdoses when used normally[57], that Defendants failed to provide a warning that leaking patches could cause overdoses and death[58], and that a leak in the Friske patch did cause Kathryn Friske's overdose and death.[59]

C. Texas Law does not preclude Plaintiffs' claim for defective design

1. Texas law does not preclude strict product liability for defectively designed prescription drugs

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[55]*See id.* at pg. 6, ¶8.

[56]*Id.*

[57]*Id.* at pgs. 8-9, ¶¶ 18 & 19.

[58]*Id.* at pg. 13, ¶13.

[59]Plaintiffs' Original Complaint at pg. 6, ¶8.

Contrary to Defendants' suggestion, it is not the law in Texas that comment k to section 402A of the RESTATEMENT (SECOND) OF TORTS precludes liability for defective design as to all FDA-approved prescription drugs. Defendants cite *Hackett v. G.D. Searle & Co.*[60] to support their broadly-worded position. The defendants in *Hackett* "urged the Court to rule that all FDA-approved prescription drugs are unavoidably unsafe as a matter of law[,]" and that defendants should therefore be exempt from liability for the design of Celebrex (an FDA-approved prescription drug).[61] The Court made a statement of dictum that "[t]o allow plaintiffs to sue for defective design of prescription drugs would provide a disincentive to companies to develop new drugs and would allow juries to second-guess the FDA's approval of the drugs for marketing."[62] This seems to be the point upon which Defendants hang their hat. Notwithstanding, the Court only ruled that under Texas law and comment k of the Restatement, the *defendants in that specific case* could be held *strictly* liable only if the drug was not properly

[60]246 F.Supp.2d 591 (W.D. Tex. 2002).

[61]*Id.* at 595.

[62]*See id.*

prepared or marketed or accompanied by proper warnings.[63] Noticeably, the Court stopped short of holding that all prescription drugs were unavoidably unsafe and exempt from strict liability for design defect.[64]

Defendants also cited *Blackmon v. Am. Home Prods. Co.*[65], which held that the defendants in that case could not be held strictly liable for the design of childhood vaccines because "the language of § 22(b) [of the National Childhood Vaccine Injury Act] shows Congress's intent to foreclose all design defect claims against vaccine manufacturers."[66] The *Blackmon* court took note of Congress' consideration of comment k when the Vaccine Act was drafted, but determined that the Vaccine Act foreclosed strict liability for design defects only with respect to the vaccines at issue in the case, not all FDA-approved prescription drugs.[67]

Defendants next cite *Keene Corp. v. Rogers* to support their contention that comment k precludes design defect liability for prescription drugs.[68] The *Keene*

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[63]*Id*. (emphasis added).

[64]*See id.*

[65]328 F.Supp. 2d 659, 664 (S.D. Tex. 2004).

[66]*Id.*

[67]*Id*. at 664-65.

[68]863 S.W.2d 168, 176 (Tex. App.–Texarkana 1993, no writ.).

case pertained to workers' injured by exposure to asbestos.[69] In that case, comment k is addressed solely in the context of its application to asbestos products and is therefore entirely inapposite to the issue of whether prescription drugs in general are unavoidably unsafe as a matter of law.[70]

Defendants point to *McNeil v. Wyeth*[71], a case from the Northern District of Texas, that is supportive of their position and relies upon the dictum of the *Hackett* case. The case was appealed and the Fifth Circuit reversed the Court's order of summary judgment without addressing the question of whether a claim for design defect was permissible.

Defendants do not and cannot cite controlling authority that all FDA-approved prescription drugs are unavoidably unsafe and are exempt from claims based upon design defect.

2. Plaintiffs stated enough facts to raise a reasonable expectation that discovery will reveal evidence of the elements necessary to recover for strict product liability based upon a design defect theory

A design defect renders a product unreasonably dangerous as designed,

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[69]*Id.* at 171.

[70]*See id.* at 176.

[71]2005 WL 544222 at *6 (N.D.Tex. Mar 04, 2005) (NO. 3-02-CV-2072L).

taking into consideration the utility of the product and the risk involved in its use.[72] A plaintiff must prove that there is a safer alternative design to recover under a design-defect theory of strict liability.[73] Plaintiffs adequately pleaded facts showing that the Friske patch was unreasonably dangerous as it was designed, given its potential to leak and cause a fatal overdose.[74] Plaintiffs also identified not one, but two safer alternative designs in existence at the time the Friske patch was designed, manufactured, sold, marketed, advertised and/or supplied.[75]

3. Plaintiffs' design defect claims pertain to the design of the patch itself, not the drug it contained

Defendants argue that manufacturers cannot be held liable for an alleged design defect in a prescription drug.[76] However, Plaintiffs allege that the design of the container that was used to administer the drug is defective, as opposed to the chemical formulation of the medication itself.[77] The distinction is important due to

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[72]*Brockert v. Wyeth Pharmaceuticals, Inc.*, 287 S.W.3d 760, 769 (Tex. App.–Houston [14 Dist.] 2009, no pet.).

[73]*Id*.

[74]Plaintiffs' Original Complaint at pgs. 6-8.

[75]Plaintiffs' Original Complaint at pg. 7, ¶15, pg. 8, ¶16.

[76]See Def. Mot. at pgs. 16-17.

[77]Plaintiffs' Original Complaint, pg. 13, ¶19.

the rationale Defendants rely upon for their argument that their product is unavoidably unsafe, specifically, that the medication's benefits outweigh the hazards of its use.[78]

Here, Plaintiffs allege that other patch designs provide the same benefits insofar as they administer the medication using the same route as did the Friske patch.[79] However, the Plaintiffs allege that the safer alternative designs do not present the same hazards as the Friske patch.[80]

In any event, Plaintiffs design defect issue pertains to the patch containing the medication, rather than the medication itself. All of defendants arguments for dismissal of Plaintiffs design defect claims address prescription medications and are therefore insufficient to carry their motion.

4. Plaintiffs' claims for negligent design survive

Even if this Court finds that Plaintiffs' strict liability claims based on defective design are barred, Plaintiffs design defect claims based on negligence survive. Negligence and strict liability are functionally distinct and rely upon

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[78]See Def. Mot. at 16.

[79]Plaintiffs' Original Complaint, pgs. 6-8.

[80]*See id.*

different standards of proof under Texas law.[81] The principles of unavoidably unsafe products outlined in Restatement § 402A comment k do not apply to Plaintiffs' negligence claims, and Defendants have not challenged Plaintiffs' claims based upon negligence.

III.
MOTION FOR LEAVE TO AMEND

A District Court should "freely give leave" to amend a complaint "when justice so requires."[82] District Courts often afford plaintiffs at least one opportunity to cure pleading deficiencies before dismissing a case, unless it is clear that the defects are incurable or the plaintiffs advise the court that they are unwilling or unable to amend in a manner that will avoid dismissal.[83] In the event that this Court finds that Plaintiffs have failed to adequately state any claim within the liberal standards of notice pleading under Rule 8(a), Plaintiffs move for leave to amend their complaint to avoid dismissal of their claims with prejudice.

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[81] *Gonzales v. Caterpillar Tractor Co.*, 571 S.W.2d 867, 871 (Tex. 1978) ("While the definitions of 'negligence' and 'defective design' may have certain similar or common elements, they involve two separate theories of recovery.).

[82] FED. R. CIV. P. 15(a)(2).

[83] *Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 329 (5th Cir. 2002).

IV.
PRAYER

For the foregoing reasons, Plaintiffs request that Defendants' Motion for Partial Dismissal be denied with respect to Plaintiffs' claims for marketing defect, design defect and negligent misrepresentation, and/or that Plaintiffs' motion for leave to amend be granted, and for such further relief as to which they may be entitled.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 18th day of March, 2011, I electronically filed the foregoing with the Clerk of Court using the CM/ECF systems which will send notification of such filing to all counsel of record.

/s/ Linda Turley
Linda Turley